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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,689	03/31/2004	Anthony D. Cristillo	502615.20013	8605
26418	7590	12/08/2008		
REED SMITH, LLP ATTN: PATENT RECORDS DEPARTMENT 599 LEXINGTON AVENUE, 29TH FLOOR NEW YORK, NY 10022-7650			EXAMINER HUMPHREY, LOUISE WANG ZHIYING	
			ART UNIT 16-48	PAPER NUMBER
			MAIL DATE 12/08/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/814,689

**Applicant(s)**

CRISTILLO ET AL.

**Examiner**

LOUISE HUMPHREY

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-24 and 29-38 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action is in response to the amendment filed 20 August 2008. Claims 1-12 and 25-28 have been cancelled. Claims 13-24 and 29-38 are pending. Claims 13-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 29-38 are currently examined.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 29-33 under 35 U.S.C. §102(b) as being anticipated by González *et al.* (1999, hereinafter "González") is **maintained** for reasons of record.

The instant claims are directed to a DNA molecule comprising a nucleic acid encoding a viral protein, which comprises a deletion of the viral budding mediating motif consisting of PTAP (SEQ ID NO:1), PPX<sub>1</sub>Y (SEQ ID NO:2), YX<sub>2</sub>X<sub>3</sub>L (SEQ ID NO:3) and a combination thereof, wherein the budding mediating motif does not include any amino acids directly adjacent to the amino acid sequence.

González teaches a plasmid comprising SIV nucleic acid comprising a deletion mutation of the C-terminus of the gag gene comprising the budding mediating motif consisting of PTAP, according to Figure 1. The deletion mutant nucleic acid is introduced into a vector also comprising the coding sequence for the SIV protease. See

page 6385, left column and Figure 1. Thus, the instant invention is anticipated by González

The rejection of claims 29-38 under 35 U.S.C. §102(b) as being anticipated by Puffer *et al.* (1997) is **maintained**.

The instant claims are drawn to a DNA molecule comprising a nucleic acid encoding a deletion mutation of a retroviral Gag protein budding mediating motif comprising or consisting of YX<sub>2</sub>X<sub>3</sub>L (SEQ ID NO:3); a vector comprising the DNA molecule; and a composition comprising either the DNA molecule or the vector.

Puffer teaches a DNA construct or PCR fragment comprising a nucleic acid encoding a deletion mutation of Equine Infectious Anemia Virus (EIAV) Gag protein budding motif consisting of Y X<sub>2</sub>X<sub>3</sub>L (SEQ ID NO:3). The PCR fragment is cloned into a plasmid vector. See abstract and page 6542, left column, "Materials and Methods," and Figure 1. Thus, the instant invention is anticipated by Puffer.

### ***Response to Arguments***

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that González fails to disclose the deletion of a budding mediating motif consisting of any of the recited three amino acid sequences or a combination thereof. Examiner does not concur. First, the deletion mutation, as claimed, consists of four amino acid residues, rather than three amino acids. Second, Applicant contends that González's deletion includes PTAP. However, Applicants cannot disregard the

open language claim limitations "a DNA molecule comprising a nucleic acid comprising a deletion mutation of the budding mediating motif" preceding the closed language "consisting of." González clearly teaches a nucleic acid comprising the deletion of a budding mediating motif consisting of PTAP.

Applicant further assert that the new limitation in the amendment "wherein the budding mediating motif does not include any amino acids directly adjacent to the amino acid sequence" clarifies the "consisting of" in claim 29. To the contrary, the new "wherein" clause merely repeats the same claim limitation as "consisting of" in a convoluted way and does not change the fact that the claim still has an open limitation for the deletion of viral budding motif.

Applicant next argues that Puffer discloses a substitution mutation of YXXL to Ala residues not a deletion mutation and that Puffer's discussion of the hypothetical function is YXXL is a far cry from disclosing a deletion mutation of a budding mediating motif consisting of YXXL. Examiner respectfully disagrees. Applicant has disregarded the pertinent section of the reference cited by the Examiner in Figure 1, specifically the construct EG.d1-28, which comprises a deletion of a viral budding motif consisting of YPDL. Applicant has shifted to an irrelevant section about alanine scanning which was never cited by the Examiner. Furthermore, Puffer's disclosure of the hypothesis about the functions of YXXL is not relevant to the claims. Puffer anticipates the claimed invention so long as the reference discloses the claimed "DNA molecule comprising a nucleic acid comprising a deletion mutation of the viral budding mediating motif consisting of YX<sub>2</sub>X<sub>3</sub>L."

**New Ground of Rejection as Necessitated by Applicant's Amendment**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites "wherein the budding mediating motif consists of an amino acid sequence" followed by the phrase "wherein the budding mediating motif does not include any amino acids directly adjacent to the amino acid sequence," which is redundant with the phrase "consisting of." It is unclear what the last wherein clause means as to whether Applicant means to limit the size of the deletion mutation or the position of the deletion mutation of the viral budding mediating motif. This rejection affects all dependent claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./  
Examiner, Art Unit 1648  
04 December 2008  
/Bruce Campell/  
Supervisory Patent Examiner, Art Unit 1648